Sugammadex compared with Neostigmine/Glycopyrrolate: An Analysis of Total PACU Time, Responsiveness, and Potential for Economic Impact

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ABSTRACT

Studies have previously shown sugammadex works faster and more effectively than neostigmine/glycopyrrolate at reversal of neuromuscular blockade by rocuronium and vecuronium. The purpose of this quality improvement study was to evaluate for differences in patient time spent in the operating room (OR), post-anesthesia care unit (PACU), and patient responsiveness between the sugammadex and neostigmine/glycopyrrolate groups at a small surgical center. Additionally, a cost analysis was conducted to assess potential savings associated with sugammadex use, taking into account the differences in OR time, PACU time, and medication acquisition cost. We conducted a prospective analysis of OR time, PACU time, and responsiveness for a total of 152 patients, 76 patients receiving neostigmine/glycopyrrolate and 76 patients receiving sugammadex, undergoing planned surgery over an 8-week period. We identified an average decrease in total OR time of 6 minutes in the sugammadex group (neostigmine/glycopyrrolate [Mean: 86 min, Median: 77 min, Range 32-211 min] vs sugammadex [Mean: 80 min, Median: 77 min, Range 40-150 min]). Furthermore, there was an average decrease in total PACU time of 6 minutes in the sugammadex group (neostigmine/glycopyrrolate [Mean: 60 min, Median: 56 min, Range 32-154 min] vs sugammadex [Mean: 54 min, Median: 51 min, Range: 28-94 min]). Additionally, the percent of patients fully awake at the end of PACU stay was higher in the sugammadex group than the neostigmine/glycopyrrolate group (86% vs 79% respectively). Cost was evaluated for generating hypotheses. The additional cost of using sugammadex was estimated at $77 per person when compared to neostigmine/glycopyrrolate. However, if the use of sugammadex decreased the time in OR and PACU by an average of 12 minutes per patient, it is possible that it could provide a potential savings of $579 per patient after estimating a soft savings of reduced OR, PACU, and staff time. Overall cost saving per patient with sugammadex, which was calculated after subtracting additional medication acquisition cost, is $502. It is possible that if this value is extrapolated to 988 patients, this might suggest a potential cost savings of $495,976 per year. We hope this study provokes future research to determine if Sugammadex is a potentially viable economical option for the routine reversal of neuromuscular blockade.

Keywords: sugammadex, neostigmine, glycopyrrolate, post-anesthesia care unit, operating room, economic evaluation, cost analysis

INTRODUCTION

Neuromuscular blocking agents (NMBAs) are used as an adjunct to anesthesia prior to surgery to paralyze vocal cords for intubation. NMBAs can be divided into two categories, depolarizing and nondepolarizing. Depolarizing NMBAs agonize cholinergic receptors of the neuromuscular junction, initially causing contraction followed by relaxation.[1] In contrast, nondepolarizing NMBAs compete with acetylcholine receptors and inhibit their action.[2]

Reversal of neuromuscular blockade (NMB) can occur by spontaneous recovery or in routine surgical practice by administration of reversal agents. Residual muscular paralysis, a persistent post-operative muscle weakness, is a dangerous risk factor for anesthesia related morbidity and mortality including airway obstruction, reintubation, hypoxia, atelectasis, aspiration, pneumonia, and pulmonary edema.[3] Furthermore, postoperative residual paralysis can decrease the efficiency of the institution by delaying transfer to the recovery room.[4]

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Neostigmine has been used routinely as a reversal agent for neuromuscular blockade since 1931.[5] Neostigmine works by inhibiting destruction of acetylcholine, which also results in unwanted muscarinic side effects including bronchospasm, intestinal hypermotility, and bradycardia.[6] Glycopyrrolate is administered in conjunction with neostigmine to minimize these adverse side effects by competitively binding to the muscarinic receptors and inhibit cholinergic transmission.[7]

Sugammadex was FDA approved in 2015 and has a novel mechanism of action. It works by selectively binding and forming a complex with the NMBAs (rocuronium and vecuronium) in the plasma, reducing the amount of NMBA available in the neuromuscular junction, reversing their effects.[8]

Studies have previously shown that sugammadex works faster and more effectively than neostigmine/glycopyrrolate for routine reversal of neuromuscular blockade by rocuronium and vecuronium.[9,10] Train-of-four (TOF) twitch stimulation is a standardized clinical tool that is used to assess the degree of neuromuscular blockade in the anesthetized patient and involves stimulating the ulnar nerve with four supramaximal

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stimuli separated by 0.5 seconds.[11] Twitches on a TOF pattern fade as relaxation increases and enables the observer to compare T4 (fourth twitch of the TOF) versus T1 (first twitch of the TOF). Train-of-four ratio (TOFR) refers to T1 to T4 ratio with a satisfactory recovery from the neuromuscular block observed at TOFR >0.9.[11]

Hristovska AM et al., conducted a meta-analysis comparing sugammadex to neostigmine with and without glycopyrrolate or atropine.[9] Among the 41 studies (n=4206) included in this meta-analysis, 12 trials (n=949) were used to assess the primary outcome (recovery times to train-of-four ratio [TOFR] > 0.9) and 28 trials were used to assess the secondary outcomes (risk of adverse events and risk of serious adverse events).[9] This meta-analysis supported sugammadex was faster than neostigmine in reversing NMB from the second twitch (T2) to TOFR > 0.9 [sugammadex 2 mg/kg (1.96 minutes) vs neostigmine 0.05 mg/kg (12.87 minutes)] and in reversing rocuronium-induced deep NMB from post-tetanic count (PTC) 1 to 5 to TOFR > 0.9 [sugammadex 4 mg/kg (2.9 minutes) vs neostigmine 0.07 mg/kg (48.8 minutes)].[9] Furthermore, patients receiving sugammadex had 40% fewer adverse events (159 composite adverse events per 1000 cases) compared with those given neostigmine alone (283 composite adverse events per 1000 cases).[9] Specifically, sugammadex showed significantly less risk of bradycardia [sugammadex (13 per 1000) vs neostigmine (84 per 1000)], postoperative nausea and vomiting [sugammadex, (68 per 1000) vs neostigmine (131 per 1000)], and postoperative residual paralysis [sugammadex (52 per 1000) vs neostigmine (131 per 1000)].[9] Application of trial sequential analysis (TSA) indicated superiority of sugammadex for recovery time and adverse events.[9]

In a multicenter, randomized, controlled trial conducted from 13 sites in Europe, patients were randomized to receive either sugammadex (2 mg/kg) or neostigmine (0.05 mg/kg) plus glycopyrrolate (0.01 mg/kg) IV.[10] The geometric mean time to recovery of the TOF ratio to 0.9 was significantly faster with sugammadex compared with neostigmine [2.7 min versus 17.9 min; P < 0.0001; two-way ANOVA].[10] Although there is sufficient evidence to support superiority of sugammadex over neostigmine and glycopyrrolate, there have been no studies to evaluate the economic value or indirect financial benefits of sugammadex use. The aim of this research was to identify if those characteristics making sugammadex more efficient could show a financial benefit. Despite several studies including a meta-analysis conducted by Carron et al. that reported sugammadex was associated with a significantly faster discharge from the OR to the PACU (mean difference [MD]=22.14 min) and the PACU to the surgical ward (MD=16.95 min), many institution have placed restrictions around sugammadex use due to the differences in drug cost.[12] Sugammadex has a higher average wholesale price than neostigmine and glycopyrrolate combined.[6,7,8] However, when evaluating the pharmacoecnomics of sugammadex, we believe it is vital to not only to consider drug acquisition cost, but to consider the financial impact of OR room cost, PACU room cost, and staff salary. It is vitally important to close the gap in knowledge regarding the economic impact of sugammadex use, as facilities will likely continue to restrict this safer and more efficacious medication, which could ultimately impact patient safety. We hypothesized that the increased cost of sugammadex could be justified by the estimated savings from a decrease in PACU time, OR time, and staff time.

METHODS

Setting

This quality improvement study was conducted at a small surgical hospital that provides clinical services to the Texas Panhandle and the surrounding tri-state area. As a quality improvement project for formulary restriction, we were not required to submit for IRB approval. Types of major surgeries performed at this hospital include arthroscopy/arthroplasty (e.g., knee, hip, disk), cholecystectomy, hysterectomy, hernia repair, salpingectomy, appendectomy, laparoscopy, discectomy, and cystectomy. Prior to our study, use of sugammadex was highly scrutinized due to its high drug acquisition cost and no internal evaluations to justify its use over neostigmine/glycopyrrolate.

Data Collection

We designed our study in a prospective manner due to insufficient data available to conduct a retrospective analysis. Inclusion criteria included any adult patient scheduled for surgery that received either sugammadex or neostigmine/glycopyrrolate without use of any other antimuscarinic (e.g., atropine). Exclusion criteria included any patient with a known allergy to sugammadex, neostigmine, or glycopyrrolate, and anyone who received another antimuscarinic (e.g., atropine) during the surgical procedure. The study period included data from September through November 2017. We collected data for two groups, separated by either treatment with neostigmine/glycopyrrolate or sugammadex, including an equal number of patients in each group. At the termination of this study, a total of 152 patients, 76 patients from sugammadex group and 76 patients from neostigmine/glycopyrrolate group, were included. During the collection period a pharmacist, a pharmacy resident, and a pharmacy technician collected and de-identified the data by reviewing patients' charts and using Docuware, a document management software for workflow automation (DocuWare, Germering, Germany). Operating room (OR) time, post anesthesia care unit (PACU) time, responsiveness, demographic information (e.g., age, sex), American Society of Anesthesiologists (ASA) scoring, and wound score were recorded for each patient. OR start time is the "enter time" of the patient into the OR. OR stop time is the time that the complete closure of the wound has occurred, as documented by a surgical nurse. OR time refers to the difference between the OR start and stop times. PACU start time is the time that the patient was transferred from the OR to the PACU. PACU stop time is the time that the patient is discharged from the PACU

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after recovery. PACU time refers to the difference between the PACU start and stop times. We assessed patient responsiveness at the end of PACU stay by physician documentation divided into three categories, not responding, arousable, and fully awake. ASA score is a global score that assesses the physical status of patients before surgery and ranges from 1-5. 1 is defined as a normal healthy patient, 2 is defined as a patient with mild systemic disease, 3 is defined as a patient with severe systemic disease, 4 is defined as a patient with severe systemic disease that is a constant threat to life, and 5 is defined as a moribund patient who is not expected to survive.[13] Wound score is based on the surgical classification ranges from 1 to 4, with 1 defined as a clean wound with no infection or inflammation, 2 defined as a clean-contaminated wound with no unusual contamination, 3 defined as a contaminated, open, fresh, accidental wound, and 4 defined as a dirty, old traumatic wound with and without existing infection or perforation.[14]

Cost Assessment

A cost assessment was conducted to generate hypotheses about sugammadex use being economically viable. We evaluated potential soft savings by estimating a potential savings by taking into account the differences in OR time, PACU time, medication acquisition cost, and anesthesiologist salary. For this research, using our actual PACU, OR, and anesthesiologist cost for publication was not permissible. We utilized previous publications to assign monetary values for our calculations of OR, PACU, and anesthesiologist cost per minute.[15,16] Estimation of 988 patients per year was calculated using 152 patients that had surgery at our institution over an 8 week period, then multiplied by 6.5 to extrapolate to patients per year. We would have liked to include other factors such as cost associated with adverse events from residual paralysis, but we were unable to include due to lack of data.

Data Analysis and Statistical Analysis

Descriptive analysis was carried out using Excel 2013. A descriptive analysis of documented data was performed to evaluate the differences in time spent in the OR, time spent in the PACU, and patient responsiveness between the sugammadex and neostigmine/glycopyrrolate groups. Statistical analysis was carried out by GraphPad Prism 7 (GraphPad Software Inc., San Diego, California, USA). Student's unpaired t-test was used to compare time spent in the OR and PACU between the sugammadex group and the neostigmine/glycopyrrolate group. Fisher's exact test was used to compare the patient responsiveness between groups.

RESULTS

Demographic representation was similar in both treatment groups, with similar sample size, average age, and sex distribution (Figure 1). Type of surgeries performed were similar in both treatment groups (Table 1). Furthermore, both groups had similar baseline physical status classifications based on the ASA scoring system [2.25 (neostigmine/glycopyrrolate) vs 2.23 (sugammadex)] (Figure 1). We included average wound score to assess severity of the surgical wounds, and both groups were similar [1.34 (neostigmine/glycopyrrolate) vs 1.23 (sugammadex)] (Figure 1).

Data analysis demonstrated that average OR time was 6 minutes shorter in the sugammadex group than in the neostigmine/glycopyrrolate group [(Mean: 80 min; Median: 77 min; Range 40-150 min; 95% CI 74-86 min vs Mean: 86 min; Median: 77 min, Range: 32-211 min; 95% CI 77-95 min, respectively) (p=0.2747, unpaired t-test)] (Table 2, Figure 2). Additionally, average PACU time was 6 minutes shorter for the sugammadex group compared to the neostigmine/glycopyrrolate group [(Mean: 54 min; Median: 51 min; Range 28-94 min; 95% CIs 50-59 min vs Mean: 60 min; Median: 56 min; Range: 32-154 min; 95% CIs 55-65 min respectively) (p=0.1054, unpaired t-test)] (Table 2, Figure 3). Percentage of patients fully awake at the end of PACU stay was higher in the sugammadex group (86%) than the neostigmine/glycopyrrolate group (79%) (p=0.3963, fisher's exact test) (Table 2, Figure 4). For the patients who were either arousable or not responding, appropriate treatment was given.

Estimated facility and personnel cost savings for sugammadex due to less time needed for anesthesiologist/facility use was $579 [$48 ($4/min x 12 minutes, Anesthesiologist) + $372 ($62/min x 6 minutes, OR room) + $159 ($26.5/min x 6 minutes, PACU room)] (Figure 5). Estimated drug acquisition cost for sugammadex, for a 75 kg patient, was $77 more for sugammadex than neostigmine/glycopyrrolate [$208 (sugammadex) - $131 (neostigmine/glycopyrrolate)] (Figure 6). For sugammadex, a single dose of 2-4 mg/kg was administered, and we chose 3 mg/kg for cost analysis because exact dose for each patient was not retrievable. For neostigmine, doses ranged between 0.03-0.07 mg/kg and we chose 0.05 mg/kg with 0.75 mg for glycopyrrolate for cost analysis because exact dose for each patient was not retrievable (Table 3). We rounded doses to vials required to account for practical application, as these medications are only available as single dose vials. Overall, potential cost savings per patient with sugammadex, which was calculated after subtracting additional medication acquisition cost, was $502 [$579 - $77] (Figure 7). If extrapolated to one year, this potential for soft-savings could equate to $495,976 annually [152 patients per 8 week study period; 152 x 6.5 = 988 patients; $502 x 988 = $495,976].

DISCUSSION

Our findings of a decrease in PACU time and OR time associated with sugammadex, although not statistically significant, are consistent with previous literature.[12] Increase in PACU time and OR time in neostigmine/glycopyrrolate could be due to onset of action being slower than sugammadex (neostigmine: 10 to 30 minutes, sugammadex: <3 minutes).[6,7,8] This could impact PACU time and OR time due to slower reversal of neuromuscular blockade requiring longer stay. Other factors that could impact PACU and OR time include increase in patients experiencing adverse events such as bradycardia. Furthermore,

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the maximum OR time and PACU time of neostigmine/glycopyrrolate was 60 minutes higher than that of sugammadex (211 minutes vs 151 minutes and 154 minutes vs 94 minutes, respectively). Yet, it has been noted that the type of surgeries performed were similar in both treatment groups, with the top 5 surgical types being arthroscopy, arthroplasty, hernia, cholecystectomy, and cystectomy. Having shorter OR and PACU times allows for faster turnover, that is ultimately beneficial to the patients and the institution. Though we evaluated 152 patients for all other parameters, 2 were excluded (1 from each group) from PACU analysis due to PACU time longer than 200 minutes and discrepancies in documentation.

Our study had several limitations. Innately there were many challenges when preparing the financial assessment. One of the limitations involves the estimation of drug acquisition cost. The exact weight and specific drug dosages were not retrievable, thus we used an estimated weight of 75 kg to calculate drug doses for cost evaluation. Additionally, using drug cost based on average wholesale price provides a good estimate; it may differ slightly from the actual hospital drug acquisition cost. A major limitation of our study is the estimated cost savings associated with minutes of OR and PACU time. We considered anesthesiologist time by using a conservative salary of approximately $340,000 per year. This could vary widely depending on actual hours worked, differences in salary, and utilization of nurse anesthetists. For the OR and PACU room costs per minute, a conservative estimate was used, but we were only able to find one single source for each estimate.[15,16] Therefore, estimation of cost could vary significantly by institution. Another limitation of our study is not documenting side effects (e.g., residual paralysis) associated with the use of each treatment, the known factor to increase an additional cost of care, and not including this in our cost analysis.

For future research, it would be beneficial to include adverse events to identify which patient populations are most likely to benefit from use of sugammadex.

Despite of these limitations, we hope that findings from this innovative study have a positive impact in suggesting that although initial acquisition of sugammadex cost is higher – it will likely pay for itself with increased efficiency of the OR and PACU. With the economic benefits of using sugammadex over neostigmine/glycopyrrolate still unknown, our study can serve as a good template for other institutions planning to conduct similar research to help evaluate the economic impact of sugammadex use.[17]

CONCLUSION

Previous studies have shown that sugammadex is faster and more efficient at reversal of neuromuscular blockade than neostigmine and glycopyrrolate. Our observation suggests a 12 minute reduction in time per surgical case possibly due to sugammadex use (6 minute decrease in OR time and a 6 minute decrease in PACU time). Sugammadex has a higher drug acquisition cost, however, when considering the potential facility and personnel cost savings, use of sugammadex could be justified at our institution. Future research still needs to be directed at identifying patient populations most likely to benefit from use of sugammadex, to assess the number of patients suffering from side effects that are known to increase economic burden to the institution, and to conduct cost-analysis to assess how reduced side effects can contribute to cost savings.

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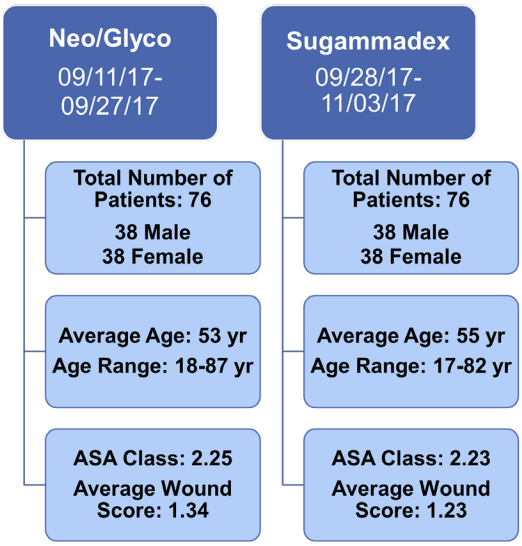
Figure 1. Demographic Representation of Two Treatment Groups



**Neo/Glyco: Neostigmine/Glycopyrrolate*

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Table 1. Types of Surgeries Conducted of Two Treatment Groups

Surgery Type	Neostigmine/ Glycopyrrolate	Sugammadex
Arthroscopy	17/76 (22%)	26/76 (34%)
Arthroplasty	13/76 (17%)	9/76 (12%)
Hernia	11/76 (14%)	10/76 (13%)
Cholecystectomy	9/76 (12%)	10/76 (13%)
Cystectomy	9/76 (12%)	10/76 (13%)
Other	10/76 (13%)	4/76 (5%)
Discectomy	1/76 (1%)	3/76 (4%)
Salpingectomy	2/76 (3%)	2/76 (3%)
Hysterectomy	2/76 (3%)	0/76 (0%)
Appendectomy	1/76 (1%)	1/76 (1%)
Laparoscopy	1/76 (1%)	1/76 (1%)
Total	76/76 (100%)	76/76 (100%)

**Data summarized as the actual number of patient/total number of patients (% of surgery) for each row*

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Table 2. Summary of Average OR Time, Average PACU Time, and Responsiveness in Two Treatment Groups

	Neostigmine/Glycopyrrolate	Sugammadex
Average OR Time	**86 minutes** (Range: 32-211 minutes)	**80 minutes** (Range: 40-150 minutes)
Average PACU Time	**60 minutes** (Range: 32-154 minutes)	**54 minutes** (Range: 28-94 minutes)
% Fully Awake	**79%**	**86%**

Table 3. Dosage for Neostigmine/Glycopyrrolate and Sugammadex

	Neostigmine/Glycopyrrolate	Sugammadex
Route of administration	**Intravenous (IV)**	**Intravenous (IV)**
Dosage	**Neostigmine: 0.03-0.07 mg/kg Glycopyrrolate: 0.75 mg**	**2-4 mg/kg**
Special Note	**Glycopyrrolate, the anticholinergic agent, was given prior to neostigmine**	**None**

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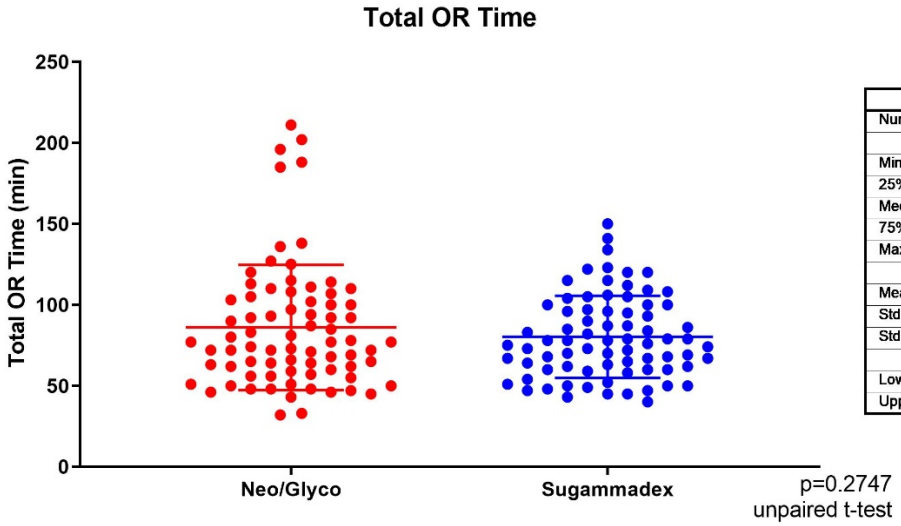
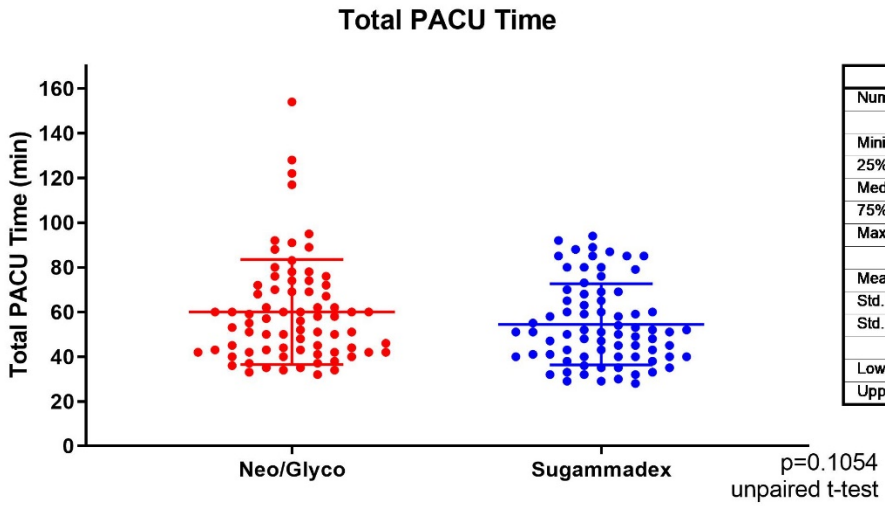
Figure 2. Patient Distribution of OR Time in Two Treatment Groups*



	Neo/Glyco	Sugammadex
Number of values	76	76
Minimum	32	40
25% Percentile	59	61
Median	77	77
75% Percentile	105	99
Maximum	211	150
Mean	86	80
Std. Deviation	39	25
Std. Error of Mean	4.4	2.9
Lower 95% CI	77	74
Upper 95% CI	95	86

**Neo/Glyco: Neostigmine/Glycopyrrolate*

Figure 3. Patient Distribution of PACU Time in Two Treatment Groups*, §



	Neo/Glyco	Sugammadex
Number of values	75	75
Minimum	32	28
25% Percentile	42	40
Median	56	51
75% Percentile	72	68
Maximum	154	94
Mean	60	54
Std. Deviation	23	18
Std. Error of Mean	2.7	2.1
Lower 95% CI	55	50
Upper 95% CI	65	59

**Neo/Glyco: Neostigmine/Glycopyrrolate*

***§** 1 patient from each group was excluded from analysis due to incomplete documentation.*

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Figure 4. Percentage of Responsiveness in Two Treatment Groups
**Neo/Glyco: Neostigmine/Glycopyrrolate*

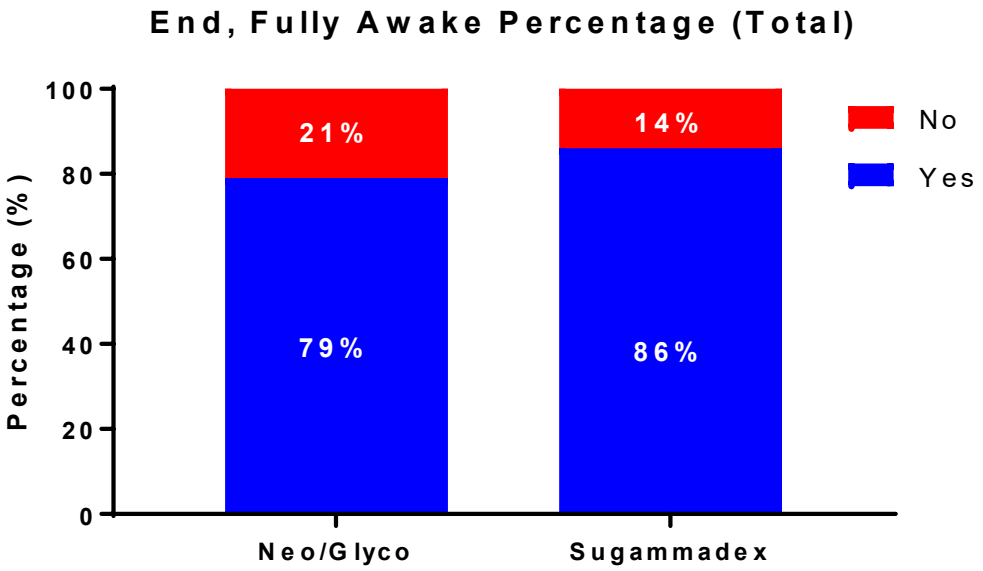

Table Analyzed	End, Fully Awake (Total)		
P value and statistical significance			
Test	Fisher's exact test		
P value	0.3963		
P value summary	ns		
One- or two-sided	Two-sided		
Statistically significant (P < 0.05)?	No		
Data analyzed	Yes	No	Total
Glyco-Neo	60	16	76
Sugammadex	65	11	76
Total	125	27	152

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Figure 5. Estimated Facility and Personnel Cost Saving Per Patient

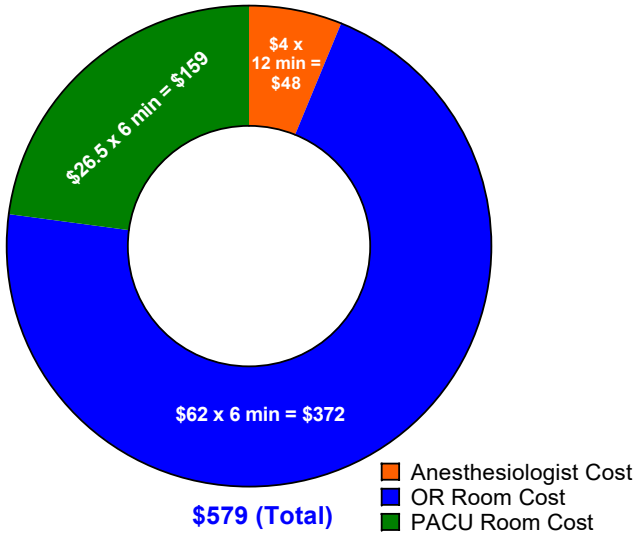

Figure 6. Estimated Drug Acquisition Cost between Two Treatments

**Neo/Glyco: Neostigmine/Glycopyrrolate*

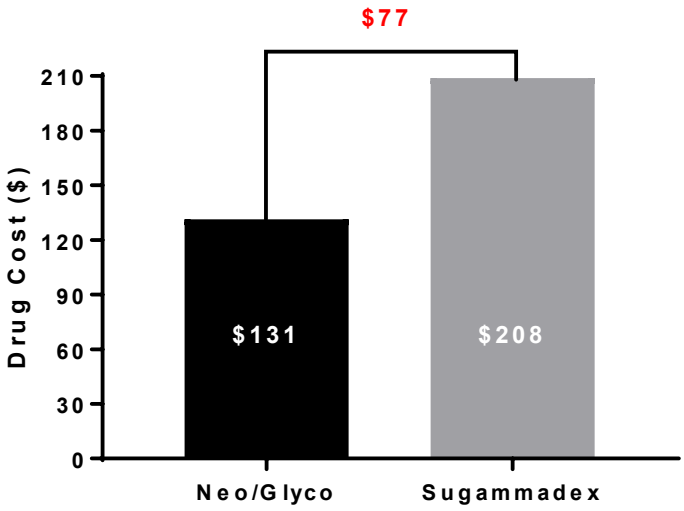

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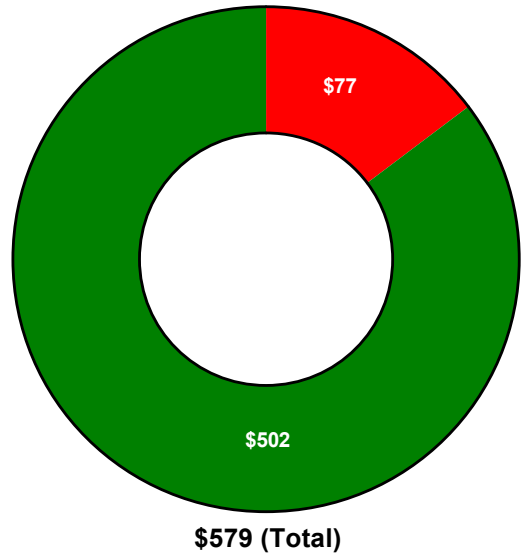
Figure 7. Overall cost saving per patient



§152 patients per 8 week study period; 1 year ~ 52 weeks; 52/8 = 6.5; 152 x 6.5 = 988 patients

DOI: https://doi.org/10.24926/iip.v10i3.1798